UNIVERSITY OF PENNSYLVANIA

School of Medicine

Department of Biochemistry and Biophysics
D501 Richards Building
Philadelphia, PA 19104-6089
Phone (21 5) 898-4342
FAX (21 5) 898-1806

October 4, 1993

Michael R. Taylor
Deputy Commission for Policy
Reference Docket 93 N-0044

Patricia Dubill
Center for Devices and Radiological Health (HFZ-84)

Department of Health and Human Services
Food and Drug Administration
21 CFR Part 1040
5600 Fishers Lane
Rockville, MD 20857

Dear Colleagues:

I've read with interest your notice of intent to allow higher intensities of light in medical devices operating in the near infrared region. I can heartily support your intent on a number of standpoints.

Item 1. 1.Many devices arc not intended for irradiating the eye.

2. The main energy deposition is in the skin and the intensities employed are well below ANSI standards for skin irradiation, as I understand it, 1 milliwatt/cm^2 in this region.

3. There is a great and pressing need to usc laser diode in a variety of instruments for which there may be important and economical and safe applications for measuring tissue properties of the breast, the brain, etc.

4. With respect to duration, a hundred seconds is more than adequate, exposure times could be limited to 30 seconds since many clinical studies require that data output be available within such a time interval.

Item 4. I do recommend that a distinction between pulsed and rapidly oscillated light intensities bc made.

Item 7. I agree that the 7 mm aperture would much morc properly be 3 m m .

Items 12 and 13 make good sense.

Restriction of remarks. This respondent dots not consider himself to be expert in classes above 1.

93N-0044

C20

Finally, the respondent takes note that medical devices are not specifically treated in this notice of intent and feels they are worthy of special consideration. For example in finger, brain and breast oximetry, the device can be attached to the particular organ prior to turning on the laser power and thus higher intensities might be appropriate.

You can certainly say in your letter please call upon me if you wish clarification or more details of my experience with research studies of medical devices under appropriate IRB approval.

Very sincerely yours,

Britton Chance

Britton Chance
Eldridge Reeves Johnson
University Professor Emeritus
of Biochemistry and Biophysics
and Physical Biochemistry and
Radiologic Physics

BC:mmg

ROUTING SLIP
GENERATED BY: **HF-40**
DATE: OCT 22,1993

FDA CONTROL NUMBER: 935170 TRACER # 0s **#:**

DATE OF CORRESPONDENCE 10/04/93 **DATE INTO FDA:** 10/22/93

TO: MICHAEL R TAYLOR I-IF-22

FROM: BRITTON CHANCE, UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE
ELDRIDGE R JOHNSON, UNIVERSITY OF PENNSYLVANIA SCHOOL OF **MEDICINE**

SYNOPSIS WRITES IN SUPPORT OF FDA'S PROPOSAL TO ALLOW HIGHER INTENSITIES OF LIGHT IN MEDICAL DEVICES OPERATING IN THE NEAR INFRARED REGION

LEAD OFFICE: **HF-40** DOCUMENT STATUS ACTIVE HOME **OFFICE: HF-40**

CONTACT/PHONE#: WANDA RUSS 301-443-39(H)

COPIES: HFZ-1
HFA-305
HF-40 ANNE M BACH
I-IF-11 NANCY B **YEATES**

COORDINATION:

SIGNATURE REQUIRED DEPUTY COMMISSIONER FOR POLICY

REFERRALS FROM **HF-40**

ASSIGNED TO		ACTION	DUE **DATE**
HF-40	GANGLOFL	PREPARE RESPONSE FOR SIGNATURE	11/07/93

REMARKS: ACKNOWLEDGEMENT **LETTER** -- PER **NYEATES**